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Substitute for form 1449A/PTO				<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	09/889,331
				Filing Date	July 13, 2001
				First Named Inventor	Young, A
				Group Art Unit	
				Examiner Name	
Sheet	1	of	4	Attorney Docket Number	030639.0031.UTL

U.S. PATENT DOCUMENTS						
Examiner Initials	Cite No ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MMDDYYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Cod& (if known)			
swl		5,264,372		Beaumont et al.	11/23/1993	
swl		5,424,286		Eng	6/13/1995	
swl		5,686,511		Bobo	11/11/1997	

Examiner Initials	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MMDDYYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ²
	Office Number	Kind Cod& (if known)					
swl	AU	199731732		Roche Diagnostics GmbH	1/5/98		
	WO	95/07098		Amylin Pharmaceuticals, Inc.	3/16/95		
	WO	98/05351		Amylin Pharmaceuticals, Inc.	2/12/98		
	WO	98/30231		Amylin Pharmaceuticals, Inc.	7/16/98		
	WO	99/07404		Amylin Pharmaceuticals, Inc.	2/18/99		
	WO	99/25727		Amylin Pharmaceuticals, Inc.	5/27/99		
	WO	99/25728		Amylin Pharmaceuticals, Inc.	5/27/99		
	WO	99/40788		Amylin Pharmaceuticals, Inc.	8/19/99		
	WO	00/41546		Amylin Pharmaceuticals, Inc.	7/20/00		
swl	WO	00/41548		Amylin Pharmaceuticals, Inc.	7/20/00		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT																	
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Sheet	2	of	4														
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<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%;">Application Number</td> <td>09/889,331</td> </tr> <tr> <td>Filing Date</td> <td>July 13, 2001</td> </tr> <tr> <td>First Named Inventor</td> <td>Young, A.</td> </tr> <tr> <td>Group Art Unit</td> <td></td> </tr> <tr> <td>Examiner Name</td> <td></td> </tr> <tr> <td colspan="2">Attorney Docket Number</td> </tr> <tr> <td colspan="2">030639.0031.UTL</td> </tr> </table>				Application Number	09/889,331	Filing Date	July 13, 2001	First Named Inventor	Young, A.	Group Art Unit		Examiner Name		Attorney Docket Number		030639.0031.UTL	
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OTHER NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
<i>swl</i>		BYRNE, M.M., et al., "Lessons from Human Studies with Glucagon-like Peptide-1: Potential of the Gut Hormone for Clinical Use," <i>Front. Diabetes</i> , 13:219-33 (1997).	*
		CHEN, Y.E., et al., "Tissue-specific Expression of Unique mRNAs That Encode Proglucagon-derived Peptides or Exendin 4 in the Lizard," <i>Journal of Biological Chemistry</i> , 272(7): 4108-4115 (1997).	
		CREUTZFELDT, W.O.C., et al., "Glucagonostatic Actions and Reduction of Fasting Hyperglycemia by Exogenous Glucagon-like Peptide I(7-36) Amide in Type I Diabetic Patients," <i>Diabetes Care</i> 19(6):580-6 (1996).	
		D'ALESSIO, et al., "Elimination of the Action of Glucagon-like Peptide 1 Causes an Impairment of Glucose Tolerance after Nutrient Ingestion by Healthy Baboons," <i>J. Clin. Invest.</i> , 97:133-38 (1996).	
		EGAN, J.M., et al., "Glucagon-like Peptide-1 Restores Acute Phase Insulin Release to Aged Rats," <i>Diabetologia</i> , 40(Supp 1):A130 abstract 505 (1997).	-
		DANIEL, O. et al., "Use of Glucagon in the Treatment of Acute Diverticulitis," <i>British Medical Journal</i> , 3:720-2, (1974).	
		EISSELE, et al., "Rat Gastric Somatostatin and Gastrin Release: Interactions of Exendin-4 and Truncated Glucagon-like Peptide-1 (GLP-1) Amide," <i>Life Sci.</i> , 55(8):629-34 (1994).	
<i>swl</i>		ENG, J., et al., "Purification and Structure of Exendin-3, a New Pancreatic Secretagogue Isolated from <i>Heloderma horridum</i> Venom," <i>J. Biol. Chem.</i> , 265(33):20259-62 (1990)	
		ENG, J., et al., "Isolation and Characterization of Exendin-	
Examiner Signature	<i>Swl</i>		Date Considered 1-28-04

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Sheet	3	of	4		

<i>swl</i>	4, an Exendin-3 Analogue, from <i>Heloderma suspectum</i> Venom," <i>J. Biol. Chem.</i> , 267(11):7402-05 (1992).
<i>swl</i>	ENG, J., "Prolonged Effect of Exendin-4 on Hyperglycemia of db/db mice," <i>Diabetes</i> , 45(Supp 2):152A (abstract 554) (1996).
	FRANCIS, et al., "PEGylation of Cytokines and Other Therapeutic Proteins and Peptides: the Importance of Biological Optimisation of Coupling Techniques," <i>International Journal of Hematology</i> , 68(1):1-18 (1998).
	GLAUSER, et al., "Intravenous Glucagon in the Management of Esophageal Food Obstruction," <i>JACEP</i> , 8:228-231 (1979).
	GOKE, et al. "Exendin-4 Is a High Potency Agonist and Truncated Exendin-(9-39)-amide an Antagonist at the Glucagon-like Peptide 1-(7-36)-amide Receptor of Insulin-secreting β -Cells," <i>J. Biol. Chem.</i> , 268(26):19650-55 (1993).
	MALHOTRA, et al., "Exendin-4, a New Peptide from <i>Heloderma Suspectum</i> Venom, Potentiates Cholecystokinin-Induced Amylase Release from Rat Pancreatic Acini," <i>Regulatory Peptides</i> , 41:149-56 (1992).
	O'HALLORAN, et al., "Glucagon-like Peptide-1 (7-36)-NH ₂ : A Physiological Inhibitor of Gastric Acid Secretion in Man," <i>J. Endocrinol.</i> , 126(1):169-73 (1990).
	ØRSKOV, et al., "Biological Effects and Metabolic Rates of Glucagonlike Peptide-1 7-36 Amide and Glucagonlike Peptide-1 7-37 in Healthy Subjects Are Indistinguishable," <i>Diabetes</i> , 42:658-61 (1993).
	PASSA, P., et al., "Mechanisms Suppressing Glucagon Secretion in Glucagonomas," <i>Diabetologia</i> , 19(3):305 [abstract 298] (1980).
	RAUERMAN, et al. "Truncated Glucagon-like Peptide-1 Interacts with Exendin Receptors in Dispersed Acini from Guinea Pig Pancreas," <i>J. Biol. Chem.</i> , 267(30):21432-37 (1992).
<i>swl</i>	SCHEPP, et al., "Exendin-4 and Exendin-(9-39)NH ₂ : Agonist and Antagonist, Respectively, at the Rat Parietal Cell

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Sheet	4	of	4	Attorney Docket Number	030639.0031.UTL

swL	Receptor for Glucagon-like Peptide-1-(7-36)NH ₂ ," <u>Eur. J. Pharm.</u> , 269:183-91 (1994).
	SCHJOLDAGER, et al., "GLP-1 (Glucagon-like Peptide 1) and Truncated GLP-1, Fragments of Human Proglucagon, Inhibit Gastric Acid Secretion in Humans," <u>Dig. Dis. Sci.</u> , 34(5):703-8 (1989).
	SINGH, et al., "Use of ¹²⁵ I-[³ H]exendin-4 to Characterize Exendin Receptors on Dispersed Pancreatic Acini and Gastric Chief Cells from Guinea Pig," <u>Regul. Pep.</u> , 53:47-59 (1994).
	STOWER, et al., "A Trial of Glucagon in the Treatment of Painful Biliary Tract Disease," <u>Br. J. Surg.</u> , 69:591-2 (1982).
	THORENS, "Expression Cloning of the Pancreatic β Cell Receptor for the Gluco-Incretin Hormone Glucagon-like Peptide 1," <u>Proc. Natl. Acad. Sci. USA</u> , 89:8641-45 (1992).
	TURTON, M.D., et al., "A Role for Glucagon-like Peptide-1 in the Central Regulation of Feeding," <u>Nature</u> , 379:69-72 (1996).
	WETTERGREN, et al., "Truncated GLP-1 (Proglucagon 78-107-Amide) Inhibits Gastric and Pancreatic Functions in Man," <u>Dig. Dis. Sci.</u> , 38(4):665-73 (1993).
swL	WILLMS, et al., "Gastric Emptying, Glucose Responses, and Insulin Secretion after a Liquid Test Meal: Effects of Exogenous Glucagon-Like Peptide-1 (GLP-1)-(7-36) Amide in Type 2 (Noninsulin-Dependent) Diabetic Patients," <u>J. Clin. Endocrinol. Metab.</u> , 81(1):327-32 (1996).

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